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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09 766,778

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04 22 2003

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/766,778

Applicant(s)

Papathanassiou

Examiner

Michael Borin

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 19, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 14-18, and 20 is/are pending in the application.
- 4a) Of the above, claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14-17, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some* c) None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachments

- | | |
|--|---|
| 1. Notice of References Cited: PTO 804 | 4. Interview Summary: PTO 806 (Paper Form) |
| 2. Notice of Draftsperson's Patent Drawing Review: PTO 948 | 5. Notice of Informal Patent Application: PTO 152 |
| 3. Information Disclosure Statement: PTO 1449, Paper No. 5 | 6. Other _____ |

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DETAILED ACTION

Status of Claims

1. Amendment filed 02/19/2003 is acknowledged. Claims 1-10,13,19 are canceled. Claims 11,12,14-18,20 are pending. Claims 11,12,20 are amended.

Examiner disagrees with applicants indication of status of claim 18: the claim is absent in the list of pending claims (p. 7, second paragraph of response). However, claim 18 has not been canceled and remains to be withdrawn from consideration as drawn to non-elected species.

In regard to election of species, SEQ ID No. 1 is being elected. Claims reading on the elected species are claims 11-17,19.

In regard to claim 20, inasmuch as the claim is amended to be dependent of claim 11, it is included again into the elected Group II.

2. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections *First Paragraph*

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3. Claims 12,14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "active" fragments comprising Kunitz-3 domain, does not reasonably provide enablement for any "active fragments of Kunitz-3 domain", as now claimed.

The claims are drawn to compositions of proteins comprising active fragments of Kunitz-3 domain having antiproliferative activity. Specification clearly states that Kunitz-3 domain, not its fragments, is required for a fragment to possess the required activity. See Example 5, and page 11, lines 25-27. There is no core structure identified as required for antiproliferative activity, nor there are examples or guidance disclosing fragments of Kunitz-3 domain having anti-proliferative activity. Further, even for more specific peptide TFPI (SEQ ID No. 1), specification does not disclose any fragments "within the amino acid sequence" of SEQ ID No. 1

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the amended claims.

Claim Rejections - 35 USC § 102 and 103

4. Claims 11-17,19 are rejected under 35 U.S.C. 102(a) as being anticipated by

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Both references teach compositions comprising TFPI (i.e. protein of instant SEQ ID No. 1) and excipients. Steinhubl et al teach that TFPI inhibits neointimal proliferation. Similarly, Khouri teaches that administration of compositions comprising TFPI inhibits intimal hyperplasia induced by arterial interventions.

The TFPI in the compositions of Steinhubl or Khouri inherently comprise any fragments as instantly claimed, Kunitz-3 domain in particular.

Response to arguments

Applicant's arguments address intended use limitations. The claims are drawn not to a method of use (as mistakenly stated on p. 9, last paragraph) but to a composition.

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure and composition, the properties applicant discloses and/or claims are necessarily present. In re Spada , 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Where the claimed and prior art products are identical or substantially identical in composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977).

5. Claim 20 is are rejected under 35 U.S.C.103(a) as obvious over Steinhubl et

The claims is drawn to a particular type (sustained release) of carrier.

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Both references teach compositions comprising TFPI (i.e. protein of instant SEQ ID No. 1) and excipients. The references do not expressly teach the particular carrier. Absent some teaching to the contrary however, selection of an appropriate pharmaceutical excipients is within the skill of the ordinary worker as a part of the process of normal optimization.

Conclusion.

5. No claims are allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

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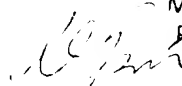
date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 17, 2003

mlb

 MICHAEL BORIN, PH.D.
PRIMARY EXAMINER